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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,956	06/27/2001	William Michael Lafferty	DIVER1280-14	7268

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EXAMINER	
FORMAN, BETTY J	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/894,956	LAFFERTY, WILLIAM MICHAEL	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 14 February 2005 in which claim 1 was. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 17 November 2004, not reiterated below, are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are discussed below as they apply to the instant grounds for rejection. New grounds for rejection, necessitated by amendment, are discussed.

Claims 1-10 and 44 are under prosecution.

Priority

Reiterated from the previous office action

2. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, parent applications 09/636,778 filed 11 August 2000; 09/098,206 filed 16 June 1998; and 08/876,276 16 June 1997 upon which priority is claimed do not provide adequate support under 35 U.S.C. 112 for claims 1-10 of this application. Specifically, the parent applications do not provide support for the instantly claimed screening apparatus comprising: plurality of capillaries held together in an array, interstitial material disposed between adjacent capillaries; and one or more reference indicia formed within the interstitial material. Therefore, the effective filing date for instant Claim 1-10 is the filing date of parent application 09/444,112 i.e. 22 November 1999.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-10 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitations "having a uniform diameter" and "retaining a sample by capillary forces only" are added to the newly amended independent claim 1 from which claims 2-10 and 44 depend. However, the specification fails to define or provide any disclosure to support such claim recitations.

Applicant cites the passage at ¶ 30 for support of the newly claimed "uniform diameter". The cited passage is provided below:

> The capillaries (20) are preferably formed with an aspect ratio of 50: 1. In one embodiment, each capillary (20) has a length of approximately lum, and an internal diameter of the lumen (40) of approximately 200gm. However, other aspect ratios are possible, and range from 10: 1 to well over 1000: 1. Accordingly, the thickness of the capillary array can vary from O.5mm to over lcm. lndividual capillaries (20) have an inner diameter that ranges from 3- 500:m and 0-500pm. A capillary (20) having an internal diameter of 200 gm and a length of 1 cm has a volume of approximately 0.3 gl. The length and width of each capillary (20) is based on a desired volume and other characteristics discussed in more detail below, such as evaporation rate of liquid from within the capillary and the like. Capillaries of the invention may include a volume as low as 250 nanoliters/well.

As noted by Applicant (page 4 of the response), the cited passage teaches the length and width of the capillary is based on desired volume. Applicant appears to be asserting that a desired volume provides a uniform diameter. However, a connection between desired volume and uniform diameter is not described or taught in the specification, nor is the capillary functionality of retaining a sample using "only" capillary forces. Therefore, the newly claimed "uniform diameter" was not described in the specification in such as way as to reasonably convey to one skilled in the art that applicant, at the time the claimed invention was made, had possession of the newly claimed invention.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application

designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 6 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Borrelli et al (U.S. Patent No. 6,350,618, filed 27 April 1999).

Regarding Claim 1, Borrelli et al disclose a sample screening apparatus comprising: a plurality of capillaries permanently bound in a non-uniform array (Fig. 2, Column 9, lines 18-34) wherein each capillary comprises at least one wall defining a lumen for retaining a sample by capillary forces (Column 10, lines 47-50); and interstitial material disposed between adjacent capillaries (e.g. sintered particles wherein following the sintering process a "honeycomb block" of channels is obtained, Column 4, line 55-Column 5, line 5). Borrelli et al further teach a uniform output opening in each tube of180 μm (Column 9, lines 33-34) wherein the device is made from bonded capillaries (Column 9, line 47 and Fig. 8).

Regarding Claim 6, Borrelli et al disclose the array wherein the lumen of each capillary has an internal diameter of between 3μ m and 500μ m (Column 9, lines 33-34).

Regarding Claim 7, Borrelli et al disclose the array wherein the plurality of capillaries are held together by being fused to one another (i.e. via sintering, Column 4, line 55-Column 5, line 5).

Response to Arguments

7. Applicant asserts that Borrelli is silent regarding uniform diameter, but in contrast teaches a device wherein the pitch of the loading end of the capillary is larger than the pitch at the delivery end. The argument has been considered but is not found persuasive because, as cited above, Borrelli teaches the redrawn/extruded capillaries having the asserted characteristics are only one preferred embodiment taught in the reference. Borrelli also teaches an embodiment wherein the diameter is uniform i.e. a uniform output opening in each tube of180 μm (Column 9, lines 33-34) wherein the device is made from bonded capillaries (Column 9, line 47 and Fig. 8).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dehlinger (U.S. Patent No. 5,763,263 issued 9 June 1998) in view of Borrelli et al (U.S. Patent No. 6,350,618, filed 27 April 1999).

Regarding Claim 1, Dehlinger discloses a sample screening apparatus comprising: a plurality of capillaries permanently bound together in an array wherein each capillary comprises at least one wall defining a lumen for retaining a sample; and interstitial material disposed between adjacent capillaries (Column 7, line 50-Column 8, line 33) wherein each capillary has a uniform diameter (Column 5, lines 5-7). Dehlinger teaches their apparatus comprises capillaries and define capillaries as "any enclosed structure capable of drawing liquid, particularly water, to a selected tube height by capillary force" (Column 7, lines 40-43). Therefore, by definition, the capillaries of Dehlinger retain sample by capillary forces.

Dehlinger specifically teaches the capillaries are arranged in a "close-packed array" (Column 8, line 17-20) but is silent regarding array uniformity. However, non-uniform arrangement of capillaries was well known in the art as taught by Borrelli et al. The arrangement illustrated by Borrelli et al provides the capillaries as closely packed as possible (i.e. with a minimum of spacing Fig. 2). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the non-uniform capillary arrangement of Borrelli et al to the capillary array of Dehlinger to thereby provide the most closely packed array they desire (Column 8, lines 17-20).

Regarding Claim 2, Dehlinger discloses the array wherein each capillary has an aspect ration of between 10:1 and 100:1 (i.e. 20-200μ inner diameter and length of 0.5 to 3 cm, Column 8, lines 3-16).

Regarding Claim 3, Dehlinger discloses the array wherein each capillary has an aspect ration of between 20:1 and 100:1 (i.e. 20-200μ inner diameter and length of 0.5 to 3 cm, Column 8, lines 3-16).

Regarding Claim 4, Dehlinger discloses the array wherein each capillary has an aspect ration of between 40:1 and 50:1 (i.e. 20-200μ inner diameter and length of 0.5 to 3 cm, Column 8, lines 3-16).

Regarding Claim 5, Dehlinger discloses the array wherein each capillary has a length of between 5m m and 10 cm (i.e. 0.5 to 3 cm, Column 8, lines 3-16).

Regarding Claim 6, Dehlinger discloses the array wherein the lumen of each capillary has an internal diameter of between 3μ m and 500μ m (i.e. 20-200μ inner diameter, Column 8, lines 3-16).

Regarding Claim 7, Dehlinger discloses the array wherein the plurality of capillaries are fused together to form the array (i.e. bonded or fixed, Column 8, lines 17-27).

Response to Applicant's comments

10. Applicant asserts that Dehlinger does not teach sample retention using only capillary force, but in contrast the reference teaches monomers attached to the interior of the capillary. The argument has been considered but is not found persuasive. The claims are drawn to an apparatus comprising capillaries "having a uniform diameter for retaining a sample by capillary forces only". The above recitation describes a diameter of the capillary i.e. sufficient for retaining a sample. Dehlinger clearly defines capillaries as having this functionality (Column 7, lines 40-43). Therefore, the capillaries of Dehlinger meet the structural limitations of the claim.

Applicant appears to be asserting that the claims are drawn to a method of retaining monomers or nucleic acids in the capillaries using only capillary forces. However, the claims are not so limited. It is noted that the courts have stated that claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

11. Claims 8-10 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dehlinger (U.S. Patent No. 5,763,263 issued 9 June 1998)) in view of Borrelli et al (U.S. Patent No. 6,350,618, filed 27 April 1999) as applied to Claim 1 above and further in view of Winkler et al (U.S. Patent No. 5,677,195).

Regarding Claim 44, Dehlinger teaches the sample screening apparatus comprising: a plurality of capillaries held together in an array wherein each capillary comprises at least one wall defining a lumen for retaining a sample; and interstitial material disposed between adjacent capillaries (Column 7, line 50-Column 8, line 33) but they do not teach the apparatus further comprises one or more reference indicia disposes within the interstitial material.

However, reference indicia within interstitial material of an array was well known in the art at the time the claimed invention was made as taught by Winkler et al who specifically teach that reference indicia are essential for consistent and precise positionally addressable array construction and use (Column 18, line 51-Column 19, line 24). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the reference indicia of Winkler et al in the capillary array of Dehlinger thereby placing reference indicia within the interstitial material of the array for the expected benefits of

consistent and precise array construction and use as taught by Winkler et al (Column 18, line 51-Column 19, line 24).

Regarding Claims 8 and 9, Dehlinger teaches their array of subarrays provides a positionally addressable device (Column 4, line 65-column 5, line 4) but they do not teach the interstitial material comprises one or more reference indicia formed at intervals (Claim 8) and formed at edges (Claim 9). However, reference indicia within interstitial material of an array was well known in the art at the time the claimed invention was made as taught by Winkler et al (Column 18, line 51-Column 19, line 24). And Winkler et al specifically teach arrays comprising reference indicia at formed at array intervals (i.e. local) and at edges (i.e. global) wherein the local and/or global indicia are essential for exact positioning and detecting of array addresses (Column 19,lines 4-39). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the local and/or global reference indicia of Winkler et al in the positionally addressable array of Dehlinger and to place the reference indicia at intervals and/or at edges of the array for the expected benefits of consistent and precise array construction and use as taught by Winkler et al (Column 18, line 51-Column 19, line 24).

Regarding Claim 10, Dehlinger teaches the array wherein capillary array comprises glass (Column 7, lines 40-47; Column 8, lines 34-44; and Column 13,line 56-Column 14, line 32) but they do not teach the array comprises reference indicia formed of glass. Winkler et al teach a similar array wherein the array comprises glass (Column 6, lines 49-60 and Column 14, lines 45-55) and they teach the array comprises reference indicia (Column 19, lines 4-24). Therefore, the reference indicia of Winkler are formed of glass as claimed. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the glass array of Dehlinger by forming reference indicia on the array as taught by Winkler et al for the expected benefits of consistent and precise array construction and use as taught by Winkler et al (Column 18, line 51-Column 19, line 24).

Response to Applicant's comments

12. Applicant reiterates the arguments discussed above regarding Dehlinger's capillaries using other than capillary force to retain the nucleic acids. The arguments have been considered as addressed above.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
April 28, 2005